May 26, 2020
Wayne, NJ, USA

GETINGE

Getinge's Cardiohelp Permitted for ECMO Use to Treat COVID-19 Patients in the US

Dear Valued Customer,

Getinge is pleased to announce that Cardiohelp (including HLS Set Advanced disposables) can be used in extracorporeal membrane oxygenation (ECMO) procedures greater than six hours for the treatment of COVID-19 patients in the U.S. This is according to guidance provided by the U.S. Food and Drug Administration (FDA) on April 6 that temporarily grants Emergency Use Authorization (EUA) and expands the availability of devices to address the public health emergency.

Getinge thanks all healthcare workers for their dedication to their patients. We are here to support you with critical ventilator and cardiopulmonary products.

Attacking the lungs, COVID-19 can trigger acute respiratory failure and/or acute cardiopulmonary failure. Under such conditions, the ECMO system can circulate the patient's blood outside of the body through an external oxygenator. The ECMO system supports the function of lungs and/or heart as the patient recovers.

Please refer to the attached IFU addendum for updated indications and instructions. These temporarily expanded indications will remain as long as the FDA guidance is in place. However, Getinge will continue to work with the FDA to develop labeling that includes patient conditions where there is a demonstrated benefit from ECMO.

Global demand for cardiopulmonary products continues to be high. Getinge has taken measures to mitigate disruptions. Production output of HLS Set Advanced disposables has already increased by 24% this year and there are additional supply expansion efforts planned and under implementation. Getinge appreciates your patience as we do everything in our ability to deliver our essential product to you.

Best regards,

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MAQUET
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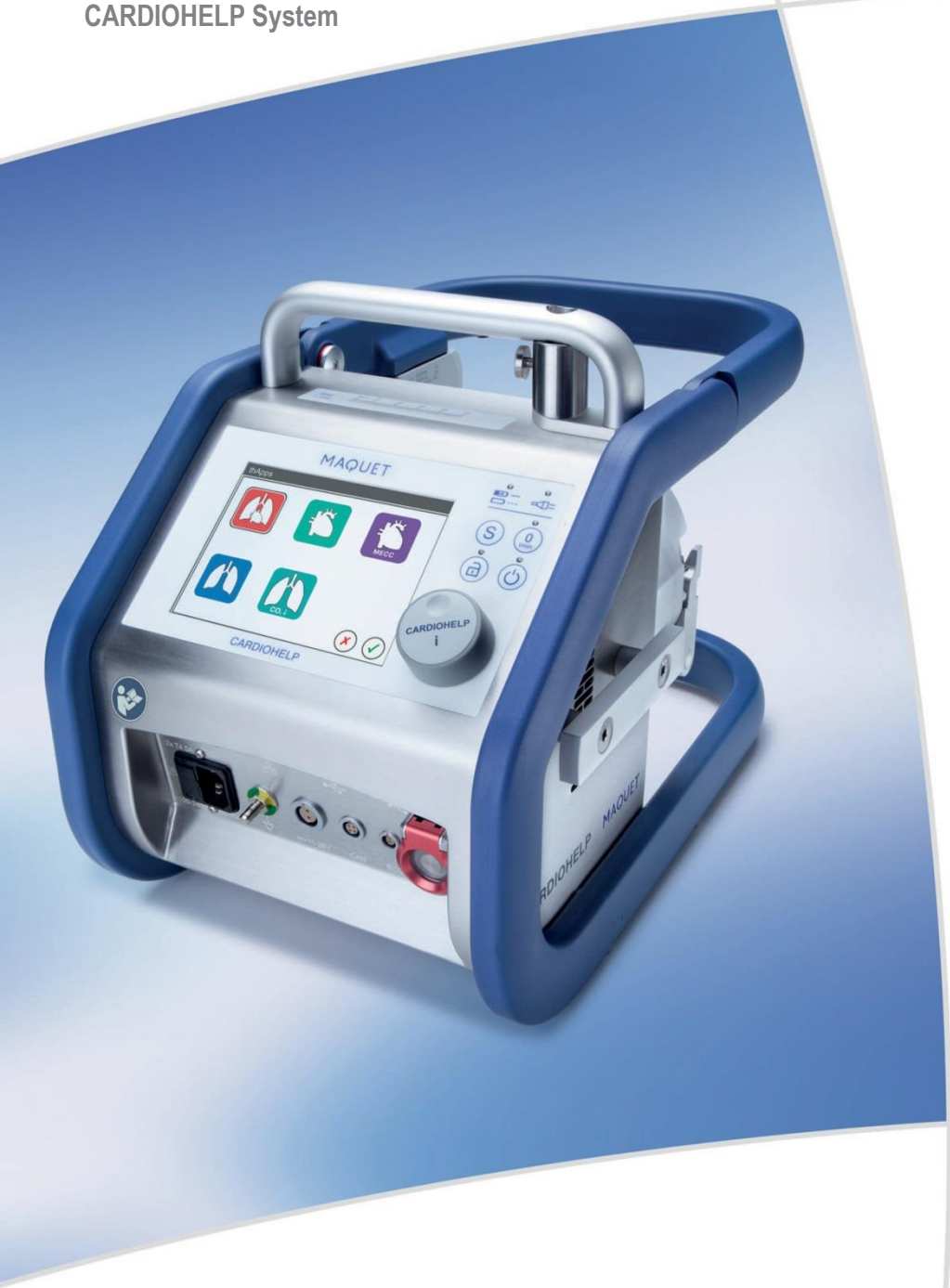
INSTRUCTIONS FOR USE

HEART-LUNG SUPPORT SYSTEM
CARDIOHELP System



(Version for Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency)

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-

1 Safety

1.1 Intended Purpose

1.1.1 Indications for Use (510(k) Premarket Notification, K133598, Cardiohelp System)

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

1.1.2 Indications for Use (Version for Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency)

The CARDIOHELP System with HLS Set Advanced is indicated for long-term (> 6 hours) respiratory/cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO2 removal) of the patient's blood in pediatric and adults with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. These may include:

- Failure to wean from cardiopulmonary bypass following cardiac surgery in pediatric and adult patients
- ECMO-assisted cardiopulmonary resuscitation in adults

The CARDIOHELP System with the HLS Set Advanced is intended to be used within the hospital environment and outside the hospital environment (e.g. during inter-hospital transport).

A series of 30-day tests have been conducted to evaluate the safety and performance of the CARDIOHELP System for extracorporeal membrane oxygenation (ECMO) when used for longer than 6 hours (up to 15 days).

[…]

4 Warnings and Precautions

4.1 Basic Safety Instructions

Unexpected pump stop or backflow prevention by bubble sensor intervention can appear giving contrast agents for diagnostics due to a difference in the acoustic properties of the fluids or during contrast echocardiography with perflutren microbubbles or other contrast agents. Using contrast agents with microbubbles can lead to venous air embolism or arterial air embolism via veno-arterial shunt. Using contrast agents with microbubbles can lead to arterial air embolism during veno-arterial application of the Cardiohelp-i.

[…]

5 Product Information

5.1 Technical Data

Sensors	Measuring range	Accuracy
Pressure	-500 … +900 mmHg	■ -500 … -151 mmHg: ±7% of the measured value
		■ -150 … +249 mmHg: ±10 mmHg
		■ +250 … +900 mmHg: ±7% of the measured value
		Offset drift: max. ±3 mmHg in 6 hours

Table 1: 510(k) Premarket Notification, K133598, Cardiohelp System

Sensors	Measuring range	Accuracy
Pressure	-500 … +900 mmHg	■ -500 … -151 mmHg: ±7% of the measured value
		■ -150 … +249 mmHg: ±10 mmHg
		■ +250 … +900 mmHg: ±7% of the measured value
	-100 … 400 mmHg	Offset drift: max. ±15 mmHg in 6 hours
		Offset drift: max. ±20 mmHg in 30 days

Table 2: Version for Coronavirus Disease 2019 (COVID-19)

[…]

7 Emergency Procedures

[…]

7.2 Indications for Replacing the Set

Replacement of the set can be indicated in the following cases:

- Leakage
- Penetration of air
- Visible deposits in the set
- Increase in pressure drop
- Insufficient oxygenation or carbon dioxide elimination at maximum gas flow or 100% FiO_2.

As far as gas transfer and pressure increase are concerned, the decision to replace the set depends on the particular situation. The indication for replacing the HLS Set Advanced is detailed below by way of example.

- An increased pressure drop can be tolerated within the limits stated above if the gas transfer and arterial blood gas analysis values are still good. If an increase in pressure drop is coupled with deteriorating gas transfer and there are indications that this development is set to continue, a replacement should be carried out as quickly as possible.
- Replacement is necessary if the pressure difference (ΔP) increases and the gas exchange capacity is significantly impaired.

Assessment of the situation and the decision whether or not to replace the set is the responsibility of the physician in charge of treatment.

Table 3: 510(k) Premarket Notification, K133598, Cardiohelp System

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